

**EPA REQUIREMENTS
FOR
QUALITY ASSURANCE PROJECT PLANS
FOR ENVIRONMENTAL DATA OPERATIONS**

EPA QA/R-5

United States Environmental Protection Agency
Quality Assurance Division

Washington, DC 20460

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U.S. Environmental Protection Agency Quality System Series

This document is one of the *U.S. Environmental Protection Agency Quality System Series* requirements and guidance documents. These documents describe the EPA policies and procedures for planning, implementing, and assessing the effectiveness of the Quality System. Requirements documents (identified as EPA QA/R-x) establish criteria and mandatory specifications for quality assurance (QA) and quality control (QC) activities. Guidance documents (identified as EPA QA/G-x) provide suggestions and recommendations of a non-mandatory nature for using the various components of the Quality System.

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FOREWORD

The U.S. Environmental Protection Agency (EPA) has developed the Quality Assurance Project Plan (QAPP) to document the type and quality of data needed for environmental decisions and to provide a blueprint for collecting and assessing those data from environmental programs. The development, review, approval, and implementation of the QAPP is an essential part of the mandatory Agency-wide Quality System.

This document contains the same requirements as Chapter 5 of the *U.S. EPA Quality Manual for Environmental Programs*, for EPA organizations. This document provides the QAPP requirements in an external publication primarily for organizations that conduct environmental data operations in behalf of EPA through contracts, financial assistance agreements, and inter-agency agreements; however, it may be used by EPA as well for specific plan requirements. A companion document provides suggestions on preparing, reviewing, and implementing QAPPs. That document is:

EPA QA/G-5 Guidance for Quality Assurance Project Plans

Effective use of this document requires that appropriate management systems for QA and QC have been implemented by the user organization. If this is not the case, the user should consult the following references for requirements for quality systems supporting EPA work:

EPA QA/R-1 EPA Quality Systems Requirements for Environmental Programs

EPA QA/R-2 EPA Requirements for Quality Management Plans

EPA QA/G-2 Guidance for Quality Management Plans

ACKNOWLEDGEMENTS

This document reflects the collaborative efforts of many quality management professionals throughout the Environmental Protection Agency, and among the contractor community, who responded to the challenge for continuous improvement in quality systems supporting environmental programs. These individuals, representing seven of the ten EPA Regional Offices, eight Program Office organizations, and eight research and development laboratories, provided a diverse and broad range of needs and insight in environmental data collection programs. Their contributions and the comprehensive reviews by members of the EPA quality community during the development of this document are greatly appreciated.

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CHAPTER I

INTRODUCTION

This document presents specifications and instructions for the information that must be contained in a Quality Assurance Project Plan (QAPP) for environmental data operations performed by or on behalf of the U.S. Environmental Protection Agency (EPA). The document also provides the procedures for QAPP review and approval. Users of this document should assume that all of the elements described herein are required in the QAPPs unless otherwise directed by EPA. *The final decision on the use of any or all of these elements for QAPPs will be made by the overseeing or sponsoring EPA organization(s).*

The EPA annually spends more than several hundred million dollars in the collection of environmental data.¹ In addition, the regulated community may spend as much as an order of magnitude more each year in complying with Agency requirements. There are several important concerns common to environmental data operations² for both the EPA and the regulated community. Both groups want to make decisions using the right data collected properly the first time.

The complexity of environmental data operations demands that a systematic process and structure for quality must be established if decision makers are to have the necessary confidence in the quality of data that support their decisions. This process and structure must include the means to determine when the data are not fully usable and what to do about the situation. This process

¹Environmental data include any parameters or pieces of information collected or produced from measurements, analyses, or models of environmental processes or conditions and effects of pollutants on human health and the ecology, including results from laboratory analyses, or from experimental systems representing such processes and conditions.

²This term is used throughout this document to refer to activities involving the acquisition, analysis, and evaluation of environmental data. See Appendix B for a more complete definition.

and structure is provided by the quality system for the organization conducting the environmental data operations. EPA policy (Ref. 1) requires that the collection of environmental data by and on behalf of the Agency be supported by a mandatory quality system. This requirement is externalized through several mechanisms, including 48 CFR 15, Part 1546, for contractors (Ref.2), 40 CFR 1, Parts 30 and 31, for financial assistance recipients (Ref. 3,4), and other mechanisms, such as consent agreements in enforcement actions.

Moreover, it is also EPA policy that all environmental data used in decision making be supported by an approved *Quality Assurance Project Plan*. The QAPP documents how QA and QC are applied to an environmental data operation to assure that the results obtained are of the type and quality needed and expected. Quality assurance (QA) and quality control (QC) are familiar terms that are related but distinct. In EPA's view, these terms are defined (Ref. 5) as follows:

- **Quality Assurance:**

An integrated system of management activities involving planning, implementation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the client.

- **Quality Control:**

The overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer; operational techniques and activities that are used to fulfill requirements for quality.

The QAPP is the principal product of the planning process inasmuch as it integrates all technical and quality aspects for the life-cycle of the project, including planning, implementation, and assessment. The purpose of the QAPP is to document planning results for environmental data operations and to provide a project-specific "blueprint" for obtaining the type and quality of environmental data needed for a specific decision or use. Implementation of the approved QAPP is expected.

The ultimate success of an environmental program or project depends on the quality of the environmental data collected and used in decision-making, and this may depend significantly on the adequacy of the QAPP and its effective implementation. This planning must include the "stakeholders" (i.e., the data users, data producers, decision makers, etc.) to ensure that all needs are defined adequately and that the planning for quality addresses the specific needs defined.

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While time spent on such planning may seem unproductive and costly, the penalty for ineffective planning includes greater cost and lost time. In the chapters to follow, the elements of the QAPP are discussed in detail. These elements represent the information that EPA believes to be necessary for data operations involving the characterization of environmental processes and conditions.

This document replaces QAMS-005/80, *Interim Guidelines and Specifications for Preparing Quality Assurance Project Plans* (Ref. 6). This document will expire five years from the official date of publication.

CHAPTER II

QUALITY ASSURANCE PROJECT PLAN REQUIREMENTS

POLICY

All work performed by or on behalf of EPA that involves the collection or use of environmental data in Agency programs shall be implemented in accordance with an Agency-approved QAPP developed from a systematic planning process based on the "graded approach"³. Work on behalf of EPA includes activities performed under contract (i.e., work assignments, technical directives, delivery orders, etc.), assistance agreement, or interagency agreement. All such work funded by EPA and involving the acquisition of environmental data generated from direct measurement activities, collected from other sources, or compiled from computerized data bases and information systems, shall **not** be implemented without an approved QAPP. Such requirements should be negotiated into applicable interagency agreements, including sub-agreements.

PURPOSE

The QAPP is a critical planning document for any environmental data operation. The QAPP documents how environmental data operations are *planned, implemented, and assessed* during the life cycle of a program, project, or task. The purpose of the QAPP is to define in detail how specific QA and QC activities will be implemented during a particular project.

APPLICABILITY

These QAPP requirements apply to all (intramural and extramural) environmental data operations that acquire, generate, or compile environmentally-related data and that are performed by or on behalf of EPA. These operations include work performed through contracts, interagency

³A graded approach is the process of basing the level of application of managerial controls applied to an item or work according to the intended use of the results and the degree of confidence needed in the quality of the results.

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agreements, and assistance agreements (e.g., cooperative agreements, grants) , and in response to statutory or regulatory requirements and consent agreements negotiated as part of enforcement actions. Where specific Federal regulations require QA/QC, QAPPs shall be prepared, reviewed, and approved in accordance with the specifications contained in this document for the data collection activity unless explicitly superseded by the regulation.

Environmental data operations encompass diverse and complex activities, and represent efforts pertaining to rulemaking, compliance with regulations, and research. Consequently, any plan developed to apply QA/QC to environmental activities **must be flexible**. This may mean, for example, that some environmental data operations, perhaps involving research projects, may only require a qualitative discussion of the experimental process and its objectives, such as a project narrative statement. Others may require extensive documentation in order to adequately describe a complex environmental program. ***This means that the content and level of detail in each QAPP will vary according to the nature of the work being performed and the intended use of the data.*** This is the concept of "graded approach." The decision on QAPP content and level of detail belongs to the EPA organization responsible for the work to be done. This is necessary to acknowledge and accommodate regulatory authorities that may exist and that may take some precedence over the results of the planning process. EPA believes that the type, quantity, and quality of environmental data needed for their intended use should be defined and documented using the Data Quality Objectives (DQO) Process (Ref. 7), or its equivalent. The results of the DQO Process provide key inputs to the QAPP and will largely determine the level of detail required in the QAPP.

SPECIAL REQUIREMENTS

In some cases, it may be necessary to add special requirements to the QAPP. The EPA organization sponsoring the work shall define any specific requirements beyond those listed in this manual. If none are specified, the QAPP shall address all required elements. Attached documentation, such as an approved Work Plan, Standard Operating Procedures (SOPs), etc., may be referenced in response to a particular required QAPP element. This is encouraged to reduce the size of the QAPP and the time required to prepare it. The QAPP shall also address related QA planning documentation (e.g., Quality Management Plans, QA Project Plans) from subcontractors or suppliers of services critical to the technical and quality objectives of the project or task. In any case, all referenced documents must be attached to the QAPP itself or be placed on file with the appropriate EPA office and available for routine referencing when needed. Such references must be kept current by the submitter.

QAPP PREPARATION RESPONSIBILITIES AND APPROVALS

The QAPP may be prepared by groups outside EPA: a contractor, an assistance agreement holder, or another Federal agency under an interagency agreement. **Except where specifically delegated, all QAPPs prepared by non-EPA organizations must be approved by**

EPA before implementation.

EPA believes that the appropriate content and level of detail in the QAPP may be best achieved by having the QAPP requirements reviewed and confirmed by the EPA project manager⁴ with the assistance and approval of the EPA QA Manager. In some cases, the authority to review and approve QAPPs is delegated to a QA Coordinator in another part of the EPA organization covered by the same Quality Management Plan (QMP). In other cases, the authority to review and approve QAPPs is delegated in writing by EPA to another organization (i.e., a state or Federal agency) when the environmental data collection program itself has been delegated to the other organization for implementation. In such cases, it is possible that the EPA Project Officer and QA Manager may not be involved in the review and approval steps.

None of the environmental work addressed by the QAPP should be started until the initial QAPP has been approved and distributed to project personnel. In limited circumstances, EPA *may* grant **conditional approval** to a QAPP to permit some work to begin while non-critical deficiencies in the QAPP are being resolved. Subject to these exceptions, it is the responsibility of the organization performing the work to assure that no environmental data are acquired before the QAPP is approved and received by project personnel.

QAPP IMPLEMENTATION AND REVISION

All QAPPs shall be implemented as approved for the intended work. The group performing the work is responsible for implementing the approved QAPP and to ensure that all personnel involved in the work have copies of the approved QAPP and all other necessary planning documents. These personnel should understand the requirements prior to the start of data generation activities.

Because of the complex and diverse nature of environmental data operations, changes to original plans are often needed. When such changes occur, the EPA Project Manager must determine if the change significantly impacts the technical and quality objectives of the project. This determination should be made in consultation with the EPA QA Manager. When a substantive change is warranted, the originator of the QAPP shall modify the QAPP to document the change and submit the revision for approval by the same authorities that performed the original review. Only after the revision has been approved and received (at least verbally with written follow-up) by project personnel, shall the change be implemented.

It is absolutely essential that the QAPP be kept current and that all personnel involved in the work effort have easy access to a current version of the QAPP. For programs or projects of

⁴This term refers to the responsible EPA official for the project and includes such descriptors as Project Officer, Delivery Order Project Officer, Work Assignment Manager, and Principal Investigator.

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long duration, such as multi-year monitoring programs, the QAPPs shall be reviewed at least annually by the Project Manager. When revisions are necessary to reflect current needs, the QAPP must be revised and resubmitted for review and approval.

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CHAPTER III

QAPP ELEMENTS

The QAPP must provide sufficient detail to demonstrate that:

- the project technical and quality objectives (i.e., Data Quality Objectives, when used) are identified and agreed upon;
- the intended measurements or data acquisition methods are appropriate for achieving project objectives;
- assessment procedures are sufficient for confirming that data of the type and quality needed and expected are obtained; and
- any limitations on the use of the data can be identified and documented.

Most environmental data operations require the coordinated efforts of many individuals, possibly including managers, engineers, scientists, statisticians, and others. The QAPP must integrate the contributions and requirements of everyone involved into a clear, concise statement of what is to be accomplished, how it will be done, and by whom. It must provide understandable instructions to those who must implement the QAPP, including the field sampling team, the analytical laboratory, and the data reviewers. The use of national standards and practices and inclusion of standard operating procedures is encouraged in all aspects of the QAPP,

In order to be effective, the QAPP must specify the level or degree of QA/QC needed for the particular environmental data operations. Because this will vary according to the purpose and type of work being done, EPA believes that the graded approach should be used in planning the work. This means that the QA/QC applied to a project will be commensurate with:

- the purpose of the environmental data collection (e.g., enforcement, R&D),
- the type of work to be done (e.g., monitoring, site characterization, bench level proof of concept), and

- the intended use of the results.

The QAPP elements that follow are presented in an order corresponding to planning, implementation, and assessment. They have been grouped for convenience into four types of elements. **All elements must be addressed in the QAPP. If an element is not applicable, state this in the QAPP.** The four types of elements and their intent are summarized as follows:

- A Project Management - This group of QAPP elements covers the basic area of project management, including the project history and objectives, roles and responsibilities of the participants, etc. These elements ensure that the project has a defined goal, that the participants understand the goal and the approach to be used, and that the planning outputs have been documented.
- B Measurement/Data Acquisition - This group of QAPP elements covers all aspects of measurement systems design and implementation, ensuring that appropriate methods for sampling, analysis, data handling, and QC are employed and are properly documented.
- C Assessment/Oversight - This group of QAPP elements addresses the activities for assessing the effectiveness of the implementation of the project and associated QA/QC. The purpose of assessment is to ensure that the QAPP is implemented as prescribed.
- D Data Validation and Usability - This group of QAPP elements covers the QA activities that occur after the data collection phase of the project is completed. Implementation of these elements ensures that the data conform to the specified criteria, thus achieving the project objectives.

GROUP A **PROJECT MANAGEMENT**

This group of QAPP elements covers the basic area of project management, including the project history and objectives, roles and responsibilities of the participants, etc. These elements ensure that the project has a defined goal, that the participants understand the goal and the approach to be used, and that the planning outputs have been documented. They include:

- | | |
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| A1 | Title and Approval Sheet |
| A2 | Table of Contents |
| A3 | Distribution List |
| A4 | Project/Task Organization |
| A5 | Problem Definition/Background |

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| A6 | Project/Task Description |
| A7 | Quality Objectives and Criteria for Measurement Data |
| A8 | Project Narrative (ORD Only) |
| A9 | Special Training Requirements/Certification |
| A10 | Documentation and Records |

A1 Title and Approval Sheet

Include:

- Title of the plan
- Name of the organization(s) implementing the project
- Names, titles, signatures of appropriate approving officials and their approval dates for:

Organization's Project Manager
Organization's Quality Assurance Manager
EPA Project Manager
EPA Quality Assurance Manager
Others, as needed (e.g., State, other Federal Agency)

A2 Table of Contents

List the sections, figures, tables, references, and appendices. Document control format may be required at the option of the Project Manager and QA Manager. When required by EPA, use document control format in the upper right-hand corner of each page following the Title and Approval Sheet.

A3 Distribution List

List the individuals and their organizations who will receive copies of the approved QAPP and any subsequent revisions. Include all managers who are responsible for implementing the plan, all persons responsible for implementation, and the QA managers and representatives of all groups involved.

A4 Project/Task Organization

Identify the individuals or organizations participating in the project and discuss

their specific roles and responsibilities. Include the principal data users, the decision-makers, the project QA manager, and all persons responsible for implementation. The project quality assurance manager **must be** independent of the unit generating the data. (This does not include being independent of senior officials, such as corporate managers or agency administrators, who are nominally, but not functionally, involved in data generation, data use, or decision-making.)

Provide a concise **organization chart showing** the relationships and the lines of communication **among** all project participants. Include other data users who are outside of the organization generating the data, but for whom the data are nevertheless intended. The organization chart must also identify any subcontractor relationships relevant to environmental data operations.

A5 Problem Definition/Background

State the specific problem to be solved or decision to be made. Include sufficient background information to provide a historical perspective for this particular project.

A6 Project/Task Description

Provide a description of the work to be performed and schedule for implementation. This discussion may not need to be lengthy or overly detailed, but it should give an overall picture of how the project will resolve the problem or question described in A5. Describe in general terms the following, as needed:

- Measurements that will be made during the course of the project.
- Applicable technical, regulatory, or program-specific quality standards, criteria, or objectives.
- Any special personnel and equipment requirements.
- The assessment tools needed (i.e., program technical reviews, peer reviews, surveillances, and technical audits) for the project.
- A schedule for the work to be performed.
- Project and quality records required, including the types of reports needed.

A7 Quality Objectives and Criteria for Measurement Data

The QAPP must include a statement of the project quality objectives and measurement performance criteria. EPA supports the use of a graded approach⁵ to QA and recommends that the initial planning be accomplished using the DQO Process, which provides quality objectives based on the user's determination of tolerable error in the results. Even in those cases in which the formal DQO Process is not used, a statement of the project quality objectives and measurement performance criteria is needed. For details on the DQO Process and when it should be used, see the EPA guidance document (QA/G-4) (Ref. 7).

A8 Project Narrative

Discuss in a narrative form the following issues as they pertain to the project or task, as needed:

- work to be performed or hypothesis to be tested,
- anticipated use of the data,
- how (quantitatively or qualitatively) the success of the project or task will be determined (A7, D3),
- survey design requirements and description (B1),
- sample type and sampling location requirements (B2),
- sample handling and custody requirements (B3),
- selection of analytical methods (B4),
- calibration and performance evaluation samples for sampling and analytical methods used (B5),
- sampling or analytical instrumentation requirements (B6),
- plans for peer or readiness reviews prior to data collection (C1), and
- any on-going assessments during actual operation (oversight) (C1).

QAPP elements corresponding to the items to be addressed in the narrative are given in parentheses. The narrative should demonstrate to technical or QA reviewers that the project or task will achieve its stated quality objectives.

A9 Special Training Requirements/Certification

⁵A graded approach to QA/QC bases the level of managerial controls applied to an item or work according to the intended use of the results and the degree of confidence needed in the quality of the results.

Identify and describe any specialized training or certification requirements needed by personnel in order to successfully complete the project or task. Discuss how such training will be provided and how the necessary skills will be assured and documented.

A10 Documentation and Records

Itemize the information and records which must be included in a data report package and specify the desired reporting format. Documentation can include raw data, field logs, instrument printouts, and results of calibration and QC checks. Specify the laboratory turnaround time needed. Specify whether a field sampling and/or laboratory analysis case narrative⁶ is required to provide a complete description of any difficulties encountered during sampling or analysis.

Specify any requirements for the final disposition of records and documents, including location and length of retention period.

GROUP B MEASUREMENT/DATA ACQUISITION

This group of QAPP elements covers all aspects of measurement systems design and implementation, ensuring that appropriate methods for sampling, analysis, data handling, and QC are employed and are documented. The following QAPP elements describe the requirements related to the actual methods to be used for the:

- collection, handling, and analysis of samples;
- measured parameters obtained from other sources (e.g., data contained in a computer data base from previous sampling activities, data compiled from surveys, data taken from the literature); and
- the management (i.e., compiling, handling) of the data.

The elements include:

B1 Sampling Process Design (Experimental Design)

Case Narrative refers to an annotated summary of the analytical work performed by a laboratory that describes in narrative form what activities were performed and identifies any problems encountered. The case narrative provides additional information to user in interpreting the data received.

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| B2 | Sampling Methods Requirements |
| B3 | Sample Handling and Custody Requirements |
| B4 | Analytical Methods Requirements |
| B5 | Quality Control Requirements |
| B6 | Instrument/Equipment Testing, Inspection, and Maintenance Requirements |
| B7 | Instrument Calibration and Frequency |
| B8 | Inspection/Acceptance Requirements for Supplies and Consumables |
| B9 | Data Acquisition Requirements (Non-direct Measurements) |
| B10 | Data Management |

The methods described in these elements should have been summarized earlier in element A6. The purpose here is to provide detailed information on the methods. If the designated methods are well documented and are readily available to all project participants, citations are adequate. If these methods are not well documented, detailed copies of the methods and/or SOPs must accompany the QAPP either in the text or as attachments.

B1 Sampling Process Design (Experimental Design)

Describe the experimental design or data collection design for the project, including:

- the types and numbers of samples required,
- the design of the sampling network,
- the sampling locations and frequencies,
- sample matrices,
- measurement parameters of interest, and
- the rationale for the design.

When field screening techniques will be used to identify samples for laboratory analysis, describe the criteria for sample selection.

All measurements should be classified as critical (i.e., required to achieve project objectives) or non-critical (informational purposes only). For non-standard methods or unusual sample matrices and situations, appropriate method validation

study information is needed to confirm the performance of the method for the particular matrix. If previous validation studies are not available, they must be developed during the project and included as part of the project results. Identifying standard methods by number, date, and regulatory citation (as appropriate) is often sufficient. However, many published (and even regulatory) methods allow the user to select from various options. The method citations should state *exactly* which options are being selected.

B2 Sampling Methods Requirements

Describe the procedures for collecting samples. Identify the sampling methods and equipment, including any implementation requirements, decontamination procedures, and materials needed. Describe specific performance requirements for the method. For each sampling method, identify any support facilities needed. The discussion should also address what to do when a failure in the sampling or measurement system occurs and who is responsible for corrective action.

B3 Sample Handling and Custody Requirements

Describe the provisions for sample handling and custody, taking into account the nature of the samples, the maximum allowable sample holding times before extraction or analysis, and available shipping options and schedules.

B4 Analytical Methods Requirements

Identify the analytical methods and equipment required, including any extraction methods, laboratory decontamination procedures and materials (such as in the case of hazardous or radioactive samples), waste disposal requirements (if any), and any specific performance requirements for the method. The QAPP should also address what to do when a failure in the analytical system occurs and who is responsible for corrective action.

B5 Quality Control Requirements

Identify the QC procedures needed for each sampling, analysis, or measurement technique. For projects at or beyond the "proof-of-concept" stage and projects employing well-characterized methods, this section should list each required QC

procedure, along with the associated acceptance criteria and corrective action. (Because standard methods are often vague or incomplete in specifying QC requirements, simply relying on the cited method to provide this information is usually insufficient.) In any case, QC procedures must frequently be modified on a project-specific basis in order to meet data specifications.

Identify required QC checks, such as matrix spikes, duplicates, blanks, laboratory control samples, surrogates, or second column confirmation. State the frequency of analysis for each type of QC check, and the spike compounds and levels. State or reference the required control limits for each QC check and corrective action required when control limits are exceeded.

Describe or reference the procedures to be used to calculate each of the QC statistics, including the QC checks described in the preceding paragraph as well as precision and bias. Copies of the formulas are acceptable as long as the accompanying narrative or explanation specifies clearly how the calculations will address difficult situations such as missing data values and "less than" or "greater than" values.

B6 Instrument/Equipment Testing, Inspection, and Maintenance Requirements

Describe how inspections and acceptance testing of environmental sampling and measurement systems and their components will be performed and documented to assure their intended use as specified by the design. Identify and discuss the procedure by which final acceptance will be performed by independent personnel (e.g., personnel other than those performing the work) and/or by the EPA Project Officer. Describe how deficiencies are to be resolved, and when re-inspection will be performed.

Describe or reference how periodic preventive and corrective maintenance of measurement or test equipment shall be performed to ensure availability and satisfactory performance of the systems. Identify the equipment and/or systems requiring periodic maintenance. Discuss how the availability of critical spare parts, identified in the operating guidance and/or design specifications of the systems, will be assured and maintained.

B7 Instrument Calibration and Frequency

Identify all tools, gauges, instruments, and other sampling, measuring, and test equipment used for data collection activities affecting quality that must be con-

trolled and, at specified periods, calibrated to maintain performance within specified limits. Describe or reference how calibration will be conducted using certified equipment and/or standards with known valid relationships to nationally recognized performance standards. If no such nationally recognized standards exist, document the basis for the calibration. Identify the certified equipment and/or standards used for calibration. Indicate how records of calibration shall be maintained and be traceable to the instrument.

B8 Inspection/Acceptance Requirements for Supplies and Consumables

Describe how and by whom supplies and consumables shall be inspected and accepted for use in the project. State acceptance criteria for such supplies and consumables.

B9 Data Acquisition Requirements (Non-direct Measurements)

Identify any types of data needed for project implementation or decision making that are obtained from non-measurement sources such as computer data bases, spreadsheets, and programs, and literature files. Define acceptance criteria for the use of such data in the project. Discuss any limitations on the use of the data resulting from uncertainty in its quality and from the impact of adding more error to the results.

B10 Data Management

Describe the project data management scheme, tracing the path of the data from their generation in the field or laboratory to their final use or storage. Describe or reference the standard record-keeping procedures, document control system, and the approach used for data storage and retrieval on electronic media. Discuss the control mechanism for detecting and correcting errors and for preventing loss of data during data reduction (i.e., calculations), data reporting, and data entry to forms, reports, and databases. Provide examples of any forms or checklists to be used.

Identify and describe all data handling equipment and procedures to process, compile, and analyze the data. This includes procedures for addressing data generated as part of the project as well as data from other sources. Include any required computer hardware and software and address any specific performance requirements for the hardware/software configuration used. Describe the proce-

dures that will be followed to demonstrate acceptability of the hardware/software configuration required.

GROUP C ASSESSMENT/OVERSIGHT

This group of QAPP elements addresses the activities for assessing the effectiveness of the implementation of the project and associated QA/QC. The purpose of assessment is to ensure that the QAPP is implemented as prescribed. The elements are:

- C1 Assessments and Response Actions
- C2 Reports to Management

C1 Assessments and Response Actions

Identify the number, frequency, and type of assessment activities needed for this project. Assessments include, but are not limited to, the following:

- surveillance,
- peer review,
- management systems review,
- readiness review,
- technical systems audit,
- performance evaluation,
- audit of data quality, and
- data quality assessment.

List and describe the assessments to be used in the project. Discuss the information expected and the success criteria (i.e., goals, performance objectives, acceptance criteria specifications, etc.) for each assessment proposed. List the approximate schedule of activities. For any planned self-assessments (utilizing personnel from within the project groups), identify the participants and their exact relationship within the project organization. For independent assessments, identify the organization and person(s) that will perform the assessments. Describe how and to whom the results of the assessments will be reported.

Define the authorities of the assessors. For example, if the assessors should order a work suspension upon finding a significant condition, this section delineates clearly their authority to do so. Define explicitly the unsatisfactory conditions under which the assessors are authorized to act. Recognizing that assessments may be needed at any time during the project, provide a schedule for the assess-

ments to be performed.

Discuss how response actions to non-conforming conditions will be addressed and by whom. Identify who is responsible for implementing the response action. Describe how response actions will be verified, validated, and documented.

C2 Reports to Management

Identify the frequency and distribution of reports issued to inform management of the following:

- status of the project;
- results of performance evaluations and system audits;
- results of periodic data quality assessments; and
- significant quality assurance problems and recommended solutions.

Identify the preparer and the recipients of the reports.

GROUP D DATA VALIDATION AND USABILITY

This group of QAPP elements covers the QA activities that occur after the data collection phase of the project is completed. Implementation of these elements determines whether or not the data conform to the specified criteria, thus satisfying the project objectives. The elements are:

- | | |
|----|--|
| D1 | Data Review, Validation, and Verification Requirements |
| D2 | Validation and Verification Methods |
| D3 | Reconciliation with User Requirements |

D1 Data Review, Validation, and Verification Requirements

State the criteria used to review and validate - that is, accept, reject, or qualify - data, in an objective and consistent manner. Identify necessary project-specific calculations or algorithms for this activity.

D2 Validation and Verification Methods

Describe the process to be used for validating and verifying data, including the chain of custody for data throughout the life cycle of the project or task. Discuss

how issues shall be resolved and the authorities for resolving such issues. Describe how the results are conveyed to data users.

D3 Reconciliation With User Requirements

Describe how the results obtained from the project or task will be reconciled with the results of the DQO Process. Describe how issues will be resolved and discuss how limitations on the use of the data will be reported to decision makers.

CHAPTER IV

QAPP IMPLEMENTATION

The QAPP is the blueprint for environmental data operations. The approved QAPP must be implemented as prescribed; however, it is not inflexible. When conditions or requirements change during environmental data operations, the QAPP must be revised then reviewed and approved in the same manner as the original QAPP.

Under EPA policy, no environmental data operations may begin to collect data before the QAPP has been approved by authorized EPA personnel or other persons to whom this authority has been specifically delegated. This applies to work performed intramurally by EPA staff and extramurally by contractors and assistance agreement holders.

Specific guidance for preparing, reviewing, and approving QAPPs may be found in a companion document, EPA QA/G-5, *Guidance for Quality Assurance Project Plans* (Ref. 8). The guidance document applies the QAPP requirements given in this document for the planning, implementation, and assessment of environmental data operations and links the QAPP requirements to the DQO process. The guidance provides examples of issues and situations typically encountered when planning data collection activities.

Other guidance documents that are related to the QAPP include:

- EPA QA/G-4, *Guidance for the Data Quality Objectives Process*, and
- EPA QA/G-9, *Guidance for the Data Quality Assessment Process* (Ref. 9).

These documents provide guidance on activities critical to successful environmental data operations and complement the QAPP preparation effort.

REFERENCES

1. EPA Order 5360.1, *Policy and Program Requirements to Implement the Mandatory Quality Assurance Program*, U.S. Environmental Protection Agency, Washington, DC (April 1984).
2. 48 CFR Chapter 15, Subpart 1546.2, "Contract Quality Requirements."
3. 40 CFR Chapter 1, Part 30, "General Regulation for Assistance Programs for Other Than State and Local Governments."
4. 40 CFR Chapter 1, Part 31, "Uniform Administrative Requirements for Grants and Cooperative Agreement to State and Local Governments."
5. ISO 8402-1994, *Quality Management and Quality Assurance - Vocabulary* (April 1994).
6. QAMS-005/80, *Interim Guidelines and Specifications for Preparing Quality Assurance Project Plans*, U.S. EPA (December 1980).
- 7.. *Guidance for the Data Quality Objectives Process*, EPA QA/G-4, U.S. EPA (August 1994).
8. *Guidance for Quality Assurance Project Plans*, EPA QA/G-5 (IN PROCESS).
9. *Guidance for the Data Quality Assessment Process*, EPA QA/G-9 (IN PROCESS).

APPENDIX A

CROSSWALK BETWEEN
EPA QA/R-5 AND QAMS-005/80

QAMS-005/80 ELEMENTS

QA/R-5 ELEMENTS

| | | | |
|------|---|----|--|
| 1.0 | Title Page with Provision for Approval Signatures | A1 | Title and Approval Sheet |
| 2.0 | Table of Contents | A2 | Table of Contents |
| 3.0 | Project Description | A5 | Problem Definition/Background |
| | | A6 | Project/Task Description |
| 4.0 | Project Organization and Responsibility | A4 | Project/Task Organization |
| 5.0 | QA Objectives for Measurement Data (PARCC) | A7 | Quality Objectives and Criteria for Measurement Data |
| 6.0 | Sampling Procedures | B1 | Sampling Process Design |
| | | B2 | Sampling Methods Requirements |
| 7.0 | Sample Custody | B3 | Sample Handling and Custody Requirements |
| 8.0 | Calibration Procedures and Frequency | B7 | Instrument Calibration and Frequency |
| 9.0 | Analytical Procedures | B4 | Analytical Methods Requirements |
| 10.0 | Data Reduction, Validation, and Reporting | D1 | Data Review, Validation, and Verification Requirements |
| | | D2 | Validation and Verification Methods |
| 11.0 | Internal Quality Control Checks and Frequency | B5 | Quality Control Requirements |

APPENDIX A

CROSSWALK BETWEEN
EPA QA/R-5 AND QAMS-005/80 contd.

QAMS-005/80 ELEMENTS

QA/R-5 ELEMENTS

12.0 Performance and Systems
Audits

C1 Assessments and Response
Actions

13.0 Preventive Maintenance
Procedures and Schedules

B6 Instrument/Equipment Testing,
Inspection, and Maintenance
Requirements

14.0 Specific Routine Procedures
Used to Assess PARCC for
Measurement Parameters Involved

D3 Reconciliation with User
Requirements

15.0 Corrective Action

C1 Assessments and Response
Actions

16.0 QA Reports to Management

C2 Reports to Management

(No Corresponding QAMS-005/80 Elements)

A8 Project Narrative

A9 Special Training Requirements or
Certification

A10 Documentation and Records

B8 Inspection/Acceptance Requirements
for Supplies and Consumables

B9 Data Acquisition Requirements (Non-
direct Measurements)

B10 Data Quality Management

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APPENDIX B

TERMS AND DEFINITIONS

activity - an all-inclusive term describing a specific set of operations or related tasks to be performed, either serially or in parallel (e.g., research and development, field sampling, analytical operations, equipment fabrication), that in total result in a product or service.

assessment - the evaluation process used to measure the performance or effectiveness of a system and its elements. As used here, assessment is an all-inclusive term used to denote any of the following: audit, performance evaluation, management systems review, peer review, inspection, or surveillance.

audit (quality) - a systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

auditee - the organization being audited.

auditor - a person qualified to perform audits.

authenticate - the act of establishing an item as genuine, valid, or authoritative.

bias - the systematic or persistent distortion of a measurement process which causes errors in one direction (i.e., the expected sample measurement is different from the sample's true value).

calibration - comparison of a measurement standard, instrument, or item with a standard or instrument of higher accuracy to detect and quantify inaccuracies and to report or eliminate those inaccuracies by adjustments.

chain of custody - an unbroken trail of accountability that ensures the physical security of samples, data, and records.

characteristic - any property or attribute of a datum, item, process, or service that is distinct, describable, and/or measurable.

comparability - a measure of the confidence with which one data set can be compared to another.

completeness - a measure of the amount of valid data obtained from a measurement system compared to the amount that was expected to be obtained under correct, normal conditions.

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computer program - a sequence of instructions suitable for processing by a computer. Processing may include the use of an assembler, a compiler, an interpreter, or a translator to prepare the program for execution. A computer program may be stored on magnetic media, and be referred to as “software,” or may be stored permanently on computer chips, and be referred to as “firmware.” Computer programs covered by this Standard are those used for design analysis, data acquisition, data reduction, data storage (data bases), operation or control, and data base or document control registers when used as the controlled source of quality information.

confidentiality procedure - a procedure used to protect confidential business information (including proprietary data and personnel records) from unauthorized access.

configuration - the functional, physical, and procedural characteristics of an item, experiment, or document.

conformance - an affirmative indication or judgement that a product or service has met the requirements of the relevant specifications, contract, or regulation; also the state of meeting the requirements.

consensus standard - a standard established by a group representing a cross section of a particular industry or trade, or a part thereof.

contractor - any organization or individual that contracts to furnish services or items or perform work.

corrective action - measures taken to rectify conditions adverse to quality and, where possible, to preclude their recurrence.

client - any individual or organization for whom items or services are furnished or work performed in response to defined requirements and expectations. See also Participant and User.

data of known quality - data that have the qualitative and quantitative components associated with their derivation documented appropriately for their intended use, and when such documentation is verifiable and defensible.

data quality assessment (DQA) - a statistical and scientific evaluation of the data set to determine the validity and performance of the data collection design and statistical test, and to determine the adequacy of the data set for its intended use.

data quality objectives (DQOs) - Qualitative and quantitative statements derived from the DQO Process that clarify study technical and quality objectives, define the appropriate type of data, and specify tolerable levels of potential decision errors that will be used as the basis for establishing the quality and quantity of data needed to support decisions.

Data Quality Objectives Process - a systematic strategic planning tool based on the scientific method that identifies and defines the type, quality, and quantity of data needed to satisfy a specified use. The key elements of the process include:

- concisely defining the problem,
- identifying the decision to be made,
- identifying the key inputs to that decision,
- defining the boundaries of the study,
- developing the decision rule,
- specifying tolerable limits on potential decision errors, and
- selecting the most resource efficient data collection design.

Data quality objectives are the qualitative and quantitative outputs from the DQO Process. The DQO Process was developed originally by the U.S. Environmental Protection Agency, but has been adapted for use by other organizations to meet their specific planning requirements. (See also Graded Approach)

data usability - the process of ensuring or determining whether the quality of the data produced meets the intended use of the data.

deficiency - an unauthorized deviation from acceptable procedures or practices, or a defect in an item.

demonstrated capability - the capability to meet procurement technical and quality specifications through evidence presented by the supplier to substantiate its claims and in a manner defined by the customer.

design - specifications, drawings, design criteria, and performance requirements. Also the result of deliberate planning, analysis, mathematical manipulations, and design processes.

design change - any revision or alteration of the technical requirements defined by approved and issued design output documents and approved and issued changes thereto.

design review - a documented evaluation by a team, including personnel such as the responsible designers, the client for the work or product being designed, and a QA representative, but other than the original designers, to determine if a proposed design will meet the established design criteria and perform as expected when implemented.

document - any written or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results.

entity - that which can be individually described and considered, such as a process, product, item,

organization, or combination thereof.

environmental conditions - the description of a physical medium (e.g., air, water, soil, sediment) or biological system expressed in terms of its physical, chemical, radiological, or biological characteristics.

environmental data - any parameters or pieces of information collected or produced from measurements, analyses, or models of environmental processes, conditions, and effects of pollutants on human health and the ecology, including results from laboratory analyses or from experimental systems representing such processes and conditions.

environmental data operations - work performed to obtain, use, or report information pertaining to environmental processes and conditions.

environmental monitoring - the process of measuring or collecting environmental data.

environmental processes - manufactured or natural processes that produce discharges to or that impact the ambient environment.

environmental programs - an all-inclusive term pertaining to any work or activities involving the environment, including but not limited to: characterization of environmental processes and conditions; environmental monitoring; environmental research and development; the design, construction, and operation of environmental technologies; and laboratory operations on environmental samples.

environmental technology - an all-inclusive term used to describe pollution control devices and systems, waste treatment processes and storage facilities, and site remediation technologies and their components that may be utilized to remove pollutants or contaminants from or prevent them from entering the environment. Examples include wet scrubbers (air), soil washing (soil), granulated activated carbon unit (water), and filtration (air, water). Usually, this term will apply to hardware-based systems; however, it will also apply to methods or techniques used for pollution prevention, pollutant reduction, or containment of contamination to prevent further movement of the contaminants, such as capping, solidification or vitrification, and biological treatment.

evidentiary records - records identified as part of litigation and subject to restricted access, custody, use, and disposal.

expedited change - an abbreviated method of revising a document at the work location where the document is used when the normal change process would cause unnecessary or intolerable delay in the work.

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financial assistance - the process by which funds are provided by one organization (usually government) to another organization for the purpose of performing work or furnishing services or items. Financial assistance mechanisms include grants, cooperative agreements, and government interagency agreements.

finding - an assessment conclusion that identifies a condition having a significant effect on an item or activity. An assessment finding may be positive or negative, and is normally accompanied by specific examples of the observed condition.

grade - the category or rank given to entities having the same functional use but different requirements for quality.

graded approach - the process of basing the level of application of managerial controls applied to an item or work according to the intended use of the results and the degree of confidence needed in the quality of the results. (See Data Quality Objectives Process)

guideline - a suggested practice that is non-mandatory in programs intended to comply with a standard.

hazardous waste - any waste material that satisfies the definition of "hazardous waste" as given in 40 CFR Part 261, "Identification and Listing of Hazardous Waste."

independent assessment - an assessment performed by a qualified individual, group, or organization that is not a part of the organization directly performing and accountable for the work being assessed.

inspection - examination or measurement of an item or activity to verify conformance to specific requirements.

item - an all-inclusive term used in place of the following: appurtenance, facility, sample, assembly, component, equipment, material, module, part, product, structure, subassembly, subsystem, system, unit, documented concepts, or data.

management - those individuals directly responsible and accountable for planning, implementing, and assessing work.

management system - a structured non-technical system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for conducting work and producing items and services.

Management Systems Review (MSR) - the qualitative assessment of a data collection operation and/or organization(s) to establish whether the prevailing quality management structure, policies,

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practices, and procedures are adequate for ensuring that the type and quality of data needed are obtained.

may - denotes permission but not a requirement.

measurement and testing equipment (M&TE) - tools, gauges, instruments, sampling devices or systems used to calibrate, measure, test, or inspect in order to control or acquire data to verify conformance to specified requirements.

method - a body of procedures and techniques for performing an activity (e.g., sampling, chemical analysis, quantification) systematically presented in the order in which they are to be executed.

mixed waste - hazardous waste material as defined by 40 CFR 261 (RCRA) and mixed with radioactive waste subject to the requirements of the Atomic Energy Act.

must - denotes a requirement that has to be met.

nonconformance - a deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate; nonfulfillment of a specified requirement.

objective evidence - any documented statement of fact, other information, or record, either quantitative or qualitative, pertaining to the quality of an item or activity, based on observations, measurements, or tests which can be verified.

observation - an assessment conclusion that identifies a condition (either positive or negative) which does not represent a significant impact on an item or activity. An observation may identify a condition which does not yet cause a degradation of quality.

organization - a company, corporation, firm, enterprise, or institution, or part thereof, whether incorporated or not, public or private, that has its own functions and administration.

organization structure - the responsibilities, authorities, and relationships, arranged in a pattern, through which an organization performs its functions.

participant - when used in the context of environmental programs, an organization, group, or individual that takes part in the planning and design process and provides special knowledge or skills to enable the planning and design process to meet its objective.

peer review - a documented critical review of work generally beyond the state of the art or characterized by the existence of potential uncertainty. The peer review is conducted by qualified

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individuals (or organization) who are independent of those who performed the work, but are collectively equivalent in technical expertise (i.e., peers) to those who performed the original work. The peer review is conducted to ensure that activities are technically adequate, competently performed, properly documented, and satisfy established technical and quality requirements. The peer review is an in-depth assessment of the assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria, and conclusions pertaining to specific work and of the documentation that supports them. Peer reviews provide an evaluation of a subject where quantitative methods of analysis or measures of success are unavailable or undefined, such as in research and development.

performance evaluation (PE) - a type of audit in which the quantitative data generated in a measurement system are obtained independently and compared with routinely obtained data to evaluate the proficiency of an analyst or laboratory.

pollution prevention (P2) - an organized, comprehensive effort to systematically reduce or eliminate pollutants or contaminants prior to their generation or their release or discharge to the environment.

precision - a measure of mutual agreement among individual measurements of the same property, usually under prescribed similar conditions, expressed generally in terms of the standard deviation.

procedure - a specified way to perform an activity.

process - a set of interrelated resources and activities which transforms inputs into outputs. Examples of processes include analysis, design, data collection, operation, fabrication, and calculation.

project - an organized set of activities within a program.

qualified data - any data that have been modified or adjusted as part of statistical or mathematical evaluation, data validation, or data verification operations.

qualified services - an indication that suppliers providing services have been evaluated and determined to meet the technical and quality requirements of the client as provided by approved procurement documents and demonstrated by the supplier to the client's satisfaction.

quality - the totality of features and characteristics of a product or service that bear on its ability to meet the stated or implied needs and expectations of the user.

quality assurance (QA) - an integrated system of management activities involving planning, implementation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the client.

quality assurance program description/plan - see quality management plan

quality assurance project plan (QAPP) - a formal document describing in comprehensive detail the necessary QA, QC, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria.

quality control (QC) - the overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer; operational techniques and activities that are used to fulfill requirements for quality.

quality improvement - a management program for improving the quality of operations. Such management programs generally entail a formal mechanism for encouraging worker recommendations with timely management evaluation and feedback or implementation.

quality indicators - measurable attributes of the attainment of the necessary quality for a particular environmental decision. Indicators of quality include precision, bias, completeness, representativeness, reproducibility, comparability, and statistical confidence.

quality management - that aspect of the overall management system of the organization that determines and implements the quality policy. Quality management includes strategic planning, allocation of resources, and other systematic activities (e.g., planning, implementation, and assessment) pertaining to the quality system.

quality management plan (QMP) - a formal document that describes the quality system in terms of the organizational structure, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, and assessing all activities conducted.

quality system - a structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required QA and QC.

radioactive waste - waste material containing radionuclides, or contaminated by radionuclides, subject to the requirements of the Atomic Energy Act.

readiness review - a systematic, documented review of the readiness for the start-up or continued use of a facility, process, or activity. Readiness reviews are typically conducted before proceeding beyond project milestones and prior to initiation of a major phase of work.

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record (quality) - a document that furnishes objective evidence of the quality of items or activities and that has been verified and authenticated as technically complete and correct. Records may include photographs, drawings, magnetic tape, and other data recording media.

remediation - the process of reducing the concentration of a contaminant (or contaminants) in air, water, or soil media to a level that poses an acceptable risk to human health.

representativeness - a measure of the degree to which data accurately and precisely represent a characteristic of a population, parameter variations at a sampling point, a process condition, or an environmental condition.

reproducibility - the precision, usually expressed as variance, that measures the variability among the results of measurements of the same sample at different laboratories.

research (applied) - a process, the objective of which is to gain knowledge or understanding necessary for determining the means by which a recognized and specific need may be met.

research (basic) - a process, the objective of which is to gain fuller knowledge or understanding of the fundamental aspects of phenomena and of observable facts without specific applications toward processes or products in mind.

research development/demonstration - Systematic use of the knowledge and understanding gained from research and directed toward the production of useful materials, devices, systems, or methods, including prototypes and processes.

scientific method - the principles and processes regarded as necessary for scientific investigation, including rules for concept or hypothesis formulation, conduct of experiments, and validation of hypotheses by analysis of observations.

self-assessment - Assessments of work conducted by individuals, groups, or organizations directly responsible for overseeing and/or performing the work.

service - the result generated by activities at the interface between the supplier and the customer, and by supplier internal activities to meet customer needs. Such activities in environmental programs include design, inspection, laboratory and /or field analysis, repair, and installation.

shall - denotes a requirement that is mandatory whenever the criterion for conformance with the specification requires that there be no deviation. This does not prohibit the use of alternative approaches or methods for implementing the specification so long as the requirement is fulfilled.

should - denotes a guideline or recommendation whenever noncompliance with the specification is permissible.

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significant condition - any state, status, incident, or situation of an environmental process or condition, or environmental technology in which the work being performed will be adversely affected sufficiently to require corrective action to satisfy quality objectives or specifications and safety requirements.

specification - a document stating requirements and which refers to or includes drawings or other relevant documents. Specifications should indicate the means and the criteria for determining conformance.

software life cycle - the period of time that starts when a software product is conceived and ends when the software product is no longer available for routine use. The software life cycle typically includes a requirements phase, a design phase, an implementation phase, a test phase, an installation and check-out phase, an operation and maintenance phase, and sometimes a retirement phase.

source reduction - any practice that reduces the quantity of hazardous substances, contaminants, or pollutants.

standard operating procedure (SOP) - a written document that details the method for an operation, analysis, or action with thoroughly prescribed techniques and steps, and that is officially approved as the method for performing certain routine or repetitive tasks.

supplier - any individual or organization furnishing items or services or performing work according to a procurement document or financial assistance agreement. This is an all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, or consultant.

surveillance (quality) - continual or frequent monitoring and verification of the status of an entity and the analysis of records to ensure that specified requirements are being fulfilled.

technical review - a documented critical review of work that has been performed within the state of the art. The review is accomplished by one or more qualified reviewers who are independent of those who performed the work, but are collectively equivalent in technical expertise to those who performed the original work. The review is an in-depth analysis and evaluation of documents, activities, material, data, or items that require technical verification or validation for applicability, correctness, adequacy, completeness, and assurance that established requirements are satisfied.

technical systems audit (TSA) - a thorough, systematic, on-site, qualitative audit of facilities, equipment, personnel, training, procedures, recordkeeping, data validation, data management, and reporting aspects of a system.

Total Quality Management (TQM) - the process of applying quality management to all activities of the organization, including technical and administrative operations. See Quality Management and Quality System.

traceability - the ability to trace the history, application, or location of an entity by means of recorded identifications. In a calibration sense, traceability relates measuring equipment to national or international standards, primary standards, basic physical constants or properties, or reference materials. In a data collection sense, it relates calculations and data generated throughout the project back to the requirements for quality for the project.

user - when used in the context of environmental programs, an organization, group, or individual that utilizes the results or products from environmental programs. A user may also be the client for whom the results or products were collected or created.

validation - confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled. In design and development, validation concerns the process of examining a product or result to determine conformance to user needs.

verification - confirmation by examination and provision of objective evidence that specified requirements have been fulfilled. In design and development, validation concerns the process of examining a result of a given activity to determine conformance to the stated requirements for that activity.

work - the process of performing a defined task or activity (e.g., research and development, field sampling, analytical operations, equipment fabrication).